



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,567	04/05/2002	Jonathan Richard Anthony Roffey	040283-0196	4959

7590 09/17/2004

Bernhard D Saxe
Foley & Lardner
Washington Harbour
3000 K Street N W, suite 500
Washington, DC 20007-5143

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,567

Applicant(s)

ROFFEY ET AL.

Examiner

Rebecca L Anderson

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 17-21, 24-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-8, 10-14, 17, 24, 25 and 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-8, 10-14, 17-21, 24-26 and 28-30 are currently pending in the instant application. Claims 18-21 and 26 are withdrawn from consideration as being for non-elected subject matter and claims 1-8, 10-14, 17, 24, 25 and 28-30 are objected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 August 2004 has been entered.

Applicants Request for reconsideration of decision on petition against restriction requirement filed under 37 CFR 1.181(f) was received on 17 August 2004. A decision has not yet been rendered.

Response to Amendment

Applicants amendment filed 17 August 2004 amending claims 1, 13 and 14 to include only 5-membered rings for the A ring has not overcome the objection to the claims. The Decision on petition dated 17 June 2004 states that:

"... the tricyclic indoline in Formula (I) contains a A ring, which is a 5- or 6-member ring optionally containing one or more heteroatoms.... Thus the tricyclic indoline is **not a fixed structure** rather various tricyclic indoline structures. The various tricyclic ring systems, for examples, benz[g]indoliny, tetrahydrofuro[2,3,g]indoliny,

Art Unit: 1626

tetrahydro-pyrano[2,3-g]indoliny], have diverse chemical structures and would not be considered to be a common core. Thus there is **not a shared common** chemical structure. The restriction is deemed proper."

Although applicant has amended the claims to include only 5-membered rings for the A ring, as can be seen by the paragraph above, the tricyclic ring systems, for example, benz[g]indoliny] (a 5-membered ring for A) and tetrahydrofuro[2,3,g]indoliny] (a 5-membered ring for A), have diverse chemical structures and are not considered to have a common core or share a common chemical structure and restriction is still considered proper.

Therefore, the objection to claims 1-8, 10-14, 17, 24, 25 and 28-30 is maintained and the elected invention for search and examination is the product of the formula (I) wherein:

R1-R7 are as found in claim 1 and A is 2,3-dihydrofuryl, a process for the preparation of the product of formula (I) and a method of treatment of disorders of the central nervous system selected from depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with dementia, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension.

Response to Arguments

Applicant's arguments filed 17 August 2004 have been fully considered but they are not persuasive. Applicants arguments filed 17 August 2004 are essentially the same as the arguments filed 1 December 2003 and therefore, the response is essentially the same as the response in the office action mailed 19 March 2004.

In the response filed 17 August 2004, applicant argues that the restriction requirement arbitrarily ignores what the applicants define to be their invention. Applicant states that the $-N=C-SCH_3$ linked to a six atom ring is the significant structural element which is shared by all the alternatives and that all compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group. Applicant also argues that the combination of U.S. Patent No. 5,633,276 and 5,755,829 does not support a finding of a lack of unity of invention and that all of the pending method claims have unity of invention because they are linked by a common structure. This is not found persuasive because, the examiner points out that the structural feature present in the claims is N-aminoethyl indoline which is found in US'276. Although the variables on the N-aminoethyl indoline differ from US'276, they are not considered part of the technical feature present in the instant claims. Therefore, for essentially the same reasons as found in the previous office action, the claims herein lack unity of invention because the structural feature present in the claims is not a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Also, even if the structural feature present in the claims was the indoline group substituted at its nitrogen atom by an aminoethyl group –

Art Unit: 1626

(CH₂)(CHR₃)_pNR₁R₂, wherein R₃ is alkyl and R₁ and R₂ are H or alkyl, this would still not be considered a special technical feature which describes a contribution over the prior art as US Patent No. 5,755,829 discloses N-substituted 4-hydroxyindoline compounds wherein R₁ can be a (C₁-4) aminoalkyl radical in which the amine is nono- or disubstituted by a (C₁-4)alkyl group and the (C₁-C₄) alkyl group can be linear or branched (column 2, lines 5-51). For essentially the same reasons as stated in previous office actions, the lack of unity has been shown by the fact that the technical feature, the N-aminoethyl indoline, in common with all of the instant claims is known in the prior art and is therefore not a special technical feature which defines a contribution over the prior art. Furthermore, since the claims lack unity of invention, the examiner may determine the groups of inventions which are so linked as to form a single general inventive concept without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. In this regard, the MPEP states in section 1850 D, that

wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains

Art Unit: 1626

The alternatives in A do not have a common property or activity as a 2,3-dihydrofuryl group is not expected to react in the same way as a phenyl group. The alternatives also do not share a common structure, i.e. there is not common structure between 2,3-dihydrofuryl and other 5-membered rings, etc., and the alternatives do not belong to a recognized class of chemical compounds in the art to which the invention pertains, specifically, the classification of a furyl group or a phenyl group, etc. differs in the US classification system. Finally, in regards to the method of treatment claims, for essentially the same reasons as stated in the prior office action, it is stated that the structural feature that found in all the claims is the N-aminoethyl indoline which is not a special technical feature that defines a contribution over the prior art of record and therefore the claims lack unity of invention. Furthermore, claims to different categories of invention are considered to have unity of invention if the claims are drawn only to one of the combinations listed in 37 CFR 1.475(b).

The restriction requirement is still deemed proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Maintained Claim Objections

Claims 1-8, 10-14, 17, 24, 25 and 28-30 are objected to for containing non-elected subject matter.

Art Unit: 1626

The remaining subject matter of claims 1-8, 10-14, 17, 24, 25 and 28-30 and the subject matter of claims 18-21 and 26 that is not drawn to the above elected group stands withdrawn as being for non elected subject matter. The remaining compounds and methods which are not within the elected group, which are independent and distinct from the elected group and do not have unity with the elected group because the technical feature present in the instant claims is not a special technical feature which defines a contribution over the prior art and are withdrawn from consideration.

Compounds which are withdrawn by means of a restriction requirement are the compounds, for example, wherein: A is, cyclopentenyl, phenyl, dihydrothienyl, etc., and methods of treatment of damage to the central nervous system by trauma, stroke, neurodegenerative diseases or toxic or infective CNS diseases such as encephalitis or meningitis, thrombosis, gastrointestinal disorders such as gastrointestinal motility, diabetes insipidus, sleep apnea and conditions treatable by agonism of the 5HT₂ receptor except for depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with dementia, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension, and methods of preventing disorders of the central nervous system, damage to the central

Art Unit: 1626

nervous system, cardiovascular disorders, gastrointestinal disorders, diabetes insipidus, sleep apnea, etc.

Some specific species of the withdrawn compounds are the species of (S)-1-(benz[g]indolin-1-yl)-2-propylamine, (S)-1-(2,3,7,8-tetrahydrothieno[2,3-g]indol-1-yl)-2-propylamine, etc.

Claims 1-8, 10-14, 17, 24, 25 and 28-30 drawn solely to the elected invention identified supra would appear allowable over the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

9/14/04


for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600